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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,894	09/08/2003	Michael A. Whitt	P-3558-US	1535

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EXAMINER	
MARVICH, MARIA	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/656,894	WHITT ET AL.	
	Examiner	Art Unit	
	Maria B. Marvich, PhD	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-112* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-112* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-112 are pending in this application and subject to restriction.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-18, 30-63 and 75-91, drawn to a recombinant non-cytopathic Rhabdovirus nucleic acid, genome and particles comprising a deletion or mutation within the region encoding the matrix protein and/or a mutation in the region encoding the glycoprotein protein, classified in class 424, subclass 93.2.

II. Claims 19-29, drawn to a method of producing non-cytopathic Rhabdovirus with a mutation in the Matrix protein, classified in class 435, subclass 91.4.

III. Claims 64-74, drawn to a method of producing recombinant Rhabdovirus with a mutation in the Glycoprotein protein, classified class 435, subclass 91.4.

IV. Claims 92-93, 98 and 99, drawn to a method for treating a subject suffering from a disease associated with a gene defect by administration of a Rhabdovirus with a heterologous gene, classified in class 435, class 455.

V. Claims 94-97, drawn to a method of immunizing a subject by administration of a Rhabdovirus with an immunogen, classified in class 424, subclass 130.1.

VI. Claims 100-103, drawn to a method of cancer lysis or cancer treatment, classified in class 514, subclass 44.

VII. Claims 104-112, drawn to a method for identifying an agent that has oncolytic activity, classified in class 435, subclass 6.

The inventions are distinct each from the other because of the following reasons:

Inventions I and II-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the recombinant Rhabdovirus nucleic acid can be used to transform cells in culture for production of heterologous proteins.

Searching the inventions of Groups I and II-VII together would impose serious search burden. The inventions of Groups I and II-VII have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the nucleic acid constructs and the method of using the product are not coextensive. Prior art, which teaches the Rhabdovirus nucleic acid would not necessarily be applicable to the method of using it. Moreover, even if the product were known, the method of using the product may be novel and unobvious in view of the preamble or active steps.

Inventions II-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of producing non-

cytopathic Rhabdovirus with a mutation in the Matrix protein, the method of producing recombinant Rhabdovirus with a mutation in the Glycoprotein protein, the method for treating a subject suffering from a disease associated with a gene defect, a method of immunizing a subject with a disease, the method of cancer lysis or cancer treatment and the method for identifying an agent that has oncolytic activity are unrelated as they comprise distinct steps and utilize different products, which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. The methods of producing a recombinant Rhabdovirus comprising a mutation in the matrix protein versus one with a glycoprotein requires use of distinct nucleic acids and means of identification of the structurally distinct molecules are distinct as Rhabdovirus with a mutation in the matrix protein are selected by non-cytopathic phenotype. These methods are distinct form the methods of Groups IV-VIII as none of Groups IV-VII are drawn to methods of producing Rhabdovirus. The method of treating a subject with a gene defect versus a method of immunizing a subject versus a method of lysing cancer are all distinct as each uses structurally distinct Rhabdovirus expressing distinct molecules with distinct functions that are assayed in distinct means. As well, methods of correcting a gene defect, immunizing a patient and lysing cancer will require distinct means of administration as well as assessment of efficacy. Therefore, the methods require steps that are not required of one another. The methods of Group II-VI are distinct from methods of identifying an agent that has oncolytic activity as this method requires steps of culturing tissues, administration of agents that inhibit mitosis and treatment with agents as well as assays to determine oncolysis, which are not required of Groups II-VI. Therefore, each method is

divergent in materials and steps. For these reasons the Inventions II and III are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups II-VII each have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups II-VII together.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provision of MPEP 821.04. Process claims that depend for or otherwise include all the limitations of the patentable produce will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendment submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirements for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 USC 101, 101, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claim in light of *In re Ochiai, In re Brouwer*

and 35 USC 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 USC 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

This application contains claims directed to the following patentably distinct species: of

1) substitutions recited in claims 6, 28, 35 and 82.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 5, 19, 30 and 75 are generic.

2) heterologous nucleic acids encoding therapeutic polypeptides, immunogenic polypeptides, markers, suicide or cytokine genes (peptides).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 or 7, 30 or 36, 45 or 52, 75 or 84 are generic.

3) marker polypeptides as recited in claim 11, 40, 53 and 86.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 10, 39 and 52 are generic.

4) cytokines as recited in claim 14 and 56.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 13 and 55 are generic.

5) heterologous nucleic acids encoding therapeutic polypeptides or immunogenic polypeptides.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 20 and 64 are generic.

6) rodent, primate or human cells.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 19 is generic.

7) species of mutations that are substitutions as recited in claim 45 or deletion of residues 449-461 or fragments thereof or deletion of residues 440-449 or fragments thereof or insertion of nucleotides encoding for DAF

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 45, 64 and 75 are generic.

The species are independent or distinct because the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the

inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Nguyen, PhD can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Maria B Marvich/

Maria B Marvich, PhD
Examiner
Art Unit 1633

March 31, 2006